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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 313,292	05 13 1999	LEWIS T. WILLIAMS	1487.002	3706

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EXAMINER

BRUSCA, JOHN S

ART UNIT PAPER NUMBER

1631

DATE MAILED 12 17 2002

37

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/313,292

Applicant(s)

STACHE-CRAIN ET AL.

Examiner

John S. Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 27 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 123-130 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 123-130 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 28.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: advisory action paper 23.

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DETAILED ACTION

It is not clear from inspection of the Office copy of the application file whether the applicants received a copy of the interview summary of 23 April 2002 or the Advisory action mailed 25 April 2002. For this reason a copy of these items are attached to the applicant's copy of this Office action.

Because this Office action contains a new grounds of rejection under 35 U.S.C. § 101,

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 September 2002 has been entered.

Claim Rejections - 35 USC § 101

The rejection of claims 77, 79-84, 109, 110, and 121 under 35 U.S.C. § 101 in the Office action mailed 31 August 2001 is withdrawn in view of the cancellation of the claims in the amendment filed 27 September 2002.

35 U.S.C. §101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 127 is rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

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Claim 127, as written, does not sufficiently distinguish over polynucleotides as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified" as taught by the specification. *See* MPEP 2105.

Claim Rejections - 35 USC § 112

The rejection of claims 77, 79-84, 109, 110, and 121 under 35 U.S.C. § 112, first paragraph for lack of enablement in the Office action mailed 31 August 2001 is withdrawn in view of the cancellation of the claims in the amendment filed 27 September 2002.

The rejection under 35 U.S.C. § 112, first paragraph for lack of written description in the Office action mailed 31 August 2001 is maintained and applied to newly filed claims 123-130 for reasons of record.

Applicant's arguments filed 27 September 2002 have been fully considered but they are not persuasive. The applicants state that one of skill in the art would understand that the applicants had in their possession at the time of filing of the instant application a number of species of polynucleotides that the instant claims read on. Such species include vectors comprising inserts consisting of SEQ ID NO:972. The Rule 132 Declaration of Christopher R. Somerville reiterates these arguments. The applicants state that only one species, that of a full length cDNA is not described in the instant specification and therefore the generic claims 123-

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130 should be considered in compliance with 35 U.S.C. 112, first paragraph. However the claims read on all variants of polynucleotides that comprise any and all portions of undescribed full length cDNA sequences. It is not correct that only one species is not described, as the number of undescribed molecules cannot be readily determined without knowledge of the length of the undescribed portions of the full length cDNA sequence from which SEQ ID NO: 972 was derived. The applicants state on page 4 of their amendment filed 27 September 2002 that polynucleotides that do not have at least 150 contiguous nucleotides of SEQ ID NO: 972 would not infringe the instant claimed invention. The issue of possible infringement is not the basis of a rejection in this Office action. The applicants have failed to provide reasons for description of the claimed genus of polynucleotides in view of the lack of description of a full length sequence of the cDNA from which SEQ ID NO: 972 was derived. The applicants arguments that flanking sequences of vectors are described would be persuasive if the applicants limited the claimed invention to vectors comprising an insert consisting of SEQ ID NO: 972.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M-F 8:30-5:00.

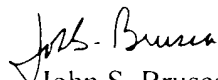
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4025. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746-5137 for regular communications and 703 746-5137 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.



John S. Brusca
Primary Examiner
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jsb
December 12, 2002